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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/316,001	05/21/1999	ROGER V. KENDALL	FSC-6	7220

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EXAMINER	
EWOLDT, GERALD R	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/316,001	Kendall et al.
Examiner	**Art Unit**
G.R. Ewoldt	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 2, 2002* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *12-18 and 20-43* is/are pending in the application.

4a) Of the above, claim(s) *22-37* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *12-18, 20, 21, and 38-43* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's amendment, drawings, and declaration under 37 CFR 1.132 of Roger V. Kendall, filed 7/02/02, are acknowledged. Said drawings have been found acceptable. In view of the amendment to Claims 12 and 15, the previous rejections under the first paragraph of 35 U.S.C. 112 and 35 U.S.C. 102(b) have been withdrawn.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 12-18, 20-21, 38-41, and newly amended Claims 42-43, stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,026,728, (1991, of record) in view of Caughey et al. (1983, of record) or Gibson et al, (1980, of record) or U.S. Patent No. 4,455,298 (1984, of record), for the reasons set forth in Papers No. 10, 17, and 22, mailed 9/26/00, 8/14/01, and 3/22/02, respectively.

Applicant arguments, filed 7/02/02, have been fully considered but are not found persuasive. Applicant continues to argue that the combination of DMG and PCE comprise significant advantages which would not have been expected from the prior art. It remains the Examiner's position that the combination of two known anti-inflammatory compositions to create an improved anti-inflammatory composition would be obvious. It further remains the Examiner's position that any modest advantages of said composition cannot be considered unexpected.

Applicant argues that the combination of DMG and PCE provides a different kind of effect than would have been expected by the prior art in that IL-10 production is significantly decreased. Additionally, Applicant asserts that CD8 and CD19 "lymphocyte markers" are reduced, as well as anti-ssDNA antibody levels. Applicant is advised that the scope of the instant claims is not commensurate with Applicant's asserted unexpected results. If said results are indeed unexpected, then the particular experimental model, product composition, and method of administration must be considered. The specification discloses a

single experiment in which a single strain of gene-deleted mice comprising a single artificial disease model are fed a single composition at a single dosage. Applicant is advised that as none of these parameters are recited in the instant claims, Applicant's asserted unexpected results cannot be considered as sufficient to render the broadly-claimed composition of the instant claims (e.g., a composition comprising any DMG or PCE components) patentably distinct from that of the prior art. As set forth in the MPEP "the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range" (see MPEP 716.02(d)).

Applicant continues to argue that the Belkowski disclosure teaches away from the combination of DMG and PCE. Again, regarding the teachings of Belkowski, said teachings can apply only to the highly artificial collagen-induced arthritis model for which a single set of non-scientifically significant results are taught. Applicant further argues that there is no evidence of record supporting the allegation that the results of the reference are insignificant. Applicant is advised that in a scientific context, results are considered to be insignificant absent a showing that they are actually statistically significant. It also remains the Examiner's position that the results of the reference cannot be said to teach away from the composition of the instant claims in its instant context, i.e., in an *lpr* mouse lupus model.

4. The following are New Grounds for Rejection necessitated by Applicant's amendment.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 12-18, 20-21, 38-41, and newly amended Claims 42-43, are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not

provide support for the invention as now claimed, specifically:

A) in Claims 12 and 15, the phrase "suitable for enteral but not parenteral administration",

B) in Claims 42-43, the phrase "not sterilized."

Applicant's amendment, filed 7/02/02, fails to assert that no new matter has been added. Applicant does state that support for the changes can be found at pages 5, lines 9-29. It is the Examiner's position, however, that support for the specific negative limitations, i.e., not parenteral and not sterilized, cannot be found in the specification.

Applicant has submitted a declaration under 37 CFR 1.132 by Roger V. Kendall in support of the invention of the instant claims. When considering the probative value of a 1.132 declaration the Examiner must consider several factors. Included in those factors are the nature of the matter sought to be established, the strength of any opposing evidence, the interest of the expert in the outcome of the case, and the presence or absence of factual support for the expert's opinion (MPEP 716.01(c)). Note the phrases "interest of the expert" and "expert's opinion." It would seem that the declarant must first be established as an expert in the field for the opinion to be of *any* probative value. In the instant case, the declarant has indicated in paragraph 3 of the declaration, "The following statements are not made as an expert in the field of the invention claimed in the above-identification [*sic*] application. Taken in combination with Mr. Kendall's likely interest in the outcome of the case (as Mr. Kendall is an inventor), it is unclear how the instant declaration can add significant patentable support to the invention of the instant claims (see MPEP 716.01(c)).

7. Applicant is advised that should the claims be amended to recite the invention previously under examination, the previous rejections under 35 U.S.C. 102(b) would be reinstated, however, the requirement to reinstate said rejections would be considered a new issue.

8. No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action

is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center at (703) 305-3014.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
October 2, 2002

Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600